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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/599,624 06/22/00 GAVIN

D 8135%

EXAMINER

027267 HM12/0910
WIGGIN & DANA LLP
ATTENTION: PATENT DOCKETING
ONE CENTURY TOWER, P.O. BOX 1832
NEW HAVEN CT 06508-1832

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ART UNIT

PAPER NUMBER

1616
DATE MAILED:

09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/599,624

Applicant(s)

GAVIN ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,28-30,36-38 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 26,27,31-35 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25,28-30,36-38 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-46 are pending in the instant application. Claims 26-27, 31, 32, 34, 35, 33, 39, 40, and 41 are withdrawn from further consideration.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, 28-30, 36-38, and 42-46, drawn to topical composition, classified in class 424, subclass 435.
- II. Claims 26-27, drawn to an anti-dandruff composition, classified in class 514, subclass 852.
- III. Claim 31, drawn to a method of treating athlete's foot, classified in class 514, subclass 858.
- IV. Claim 32, drawn to a method of treating microbial infections, classified in class 514, subclass 858.
- V. Claim 34, drawn to a method of treating fungal infections, classified in class 424, subclass 404.
- VI. Claim 35, drawn to a method of treating dandruff, classified in class 514, subclass 852.
- VII. Claim 33, drawn to a method of improving appearance, classified in class 424, subclass 132.
- VIII. Claim 39, drawn to a method of regulating hair growth, classified in class 514, subclass 852.

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IX. Claim 40, drawn to a method of stimulating hair growth, classified in class 514, subclass 852.

X. Claim 41, drawn to a method of inhibiting or reducing hair loss, classified in class 514, subclass 852.

Inventions III, IV, V, VI, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can be used for a variety of methods.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can be used a anti-fungal composition. The subcombination has separate utility such as an antidandruff composition.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Claim 1, 17, 23, and 25 are generic to a plurality of disclosed patentably distinct species comprising metal ion source and pyrithione (claim 1), surfactant (claim 17), anti-microbial active agent (claim 23), and conditioning agent (claim 25). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ms. Sivik on September 6, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-25, 29-30, 36-38, 42-46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-27, 31, 32, 33, 34, 35, 39, 40, and 41 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-25, 28-30, 36-38, and 42-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wiese (U.S. Pat. No. 5,227,156).

Wiese relates to the activity of antidandruff shampoo containing a pyrrhione and a stabilizer. Wiese teaches that zinc pyrrhione reacts adversely with some thiazolinone preservatives, which reduce its activity and its ability to prevent or reduce microbiological contamination (col. 1, lines 20-24). Wiese develops a zinc pyrrhione shampoo that contains a stable thiazolinone preservative. The shampoo is comprised of from about 0.1% to about 2.0% zinc pyrrhione, from about 0.001% to about 1.0% of a stabilizer comprising a zinc compound, and other ingredients (col. 1, lines 35-44).

Along with the preservative, a stabilizer is added to the shampoo. Suitable stabilizers are zinc compounds such as zinc salts of an organic acid, zinc salts of an inorganic acid, zinc oxide, zinc sulfates, zinc hydroxide, zinc acetate, and zinc chloride (col. 3, lines 38-45).

The shampoo further consists of up to about 40% of surfactants (anionic, nonionic, amphoteric, and zwitterionic) (col. 5, lines 30-33). Water comprises the balance of the shampoo.

As Wiese teaches using zinc pyrrhione as taught by the instant invention, notice is taken that at least 50% of the zinc pyrrhione is insoluble in the composition. In the alternative, it is taught in the prior art that zinc salts of pyridinethione are substantially insoluble in water (10-20ppm). (see, Grand, U.S. Pat. No. 3,940,482).

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2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Specifically, see Kaufman et al. (U.S. Pat. No. 6,017,562).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD

September 7, 2001



NEIL S. LEVY
PRIMARY EXAMINER